

Complete Summary

GUIDELINE TITLE

The American Association of Clinical Endocrinologists medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update.

BIBLIOGRAPHIC SOURCE(S)

American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82. [96 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Insulin dependent diabetes mellitus
- Non-insulin-dependent diabetes mellitus

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To develop a systematic multidisciplinary approach to help clinical endocrinologists and other physicians provide intensive therapy for patients with diabetes mellitus in an effort to achieve normal or near normal blood glucose levels
- To emphasize the importance of intensive diabetes self-management for type 2 diabetes because type 2 diabetes is under recognized as a very serious disease that must be treated as aggressively as type 1 diabetes
- To decrease the rate of complications, improve patients' quality of life, and decrease the total cost of care associated with both insulin dependent diabetes mellitus and non-insulin-dependent diabetes mellitus
- To present new guidelines for HbA1c levels, pre and postprandial targets, and a universal term for hemoglobin A1c
- To include changes in treatment that have occurred since the publication of the previous (2000) version of the guideline

TARGET POPULATION

Adults and children with type 1 and type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

The American Association of Clinical Endocrinologists (AACE) System of Intensive Diabetes Self-Management

Phase I. Initial patient assessment: Physical examination, laboratory examination, initial patient education and formulation of a customized therapeutic approach

Phase II. Follow-up assessments: Interim assessments of the patient's physical condition and reaction to intensive therapy, and ongoing development of the skills of the patient

Phase III. Assessment of complications: Ongoing assessment of the complications of diabetes mellitus as well as reeducation of the patient and encouragement to maintain enthusiasm for the difficult task of intensively managing blood glucose levels

MAJOR OUTCOMES CONSIDERED

- Blood glucose and insulin levels
- Glycosylated hemoglobin (HbA1c) levels
- Onset and progression of diabetic complications
- Costs of treating diabetes and diabetic complications
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American College of Endocrinology (ACE) held a Diabetes Mellitus Consensus Conference, August 20-21, 2001. The outcome of this ground breaking conference included new guidelines for HbA1c levels. Pre and postprandial targets, and a universal term for hemoglobin A1c. These guidelines have been revised to reflect these outcomes.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost and Cost-Effectiveness of Diabetes Care

The cost of diabetes mellitus is enormous, not only in terms of human morbidity and mortality but also relative to the economic burden it has imposed on the health-care system in the United States. Although patients with diabetes constitute only 3.1% of the total US population, they incur 11.9% of the total US health-care expenditures.

Factors Contributing to Costs

The economic costs of diabetes consist of direct health-care expenditures as well as the loss of productivity because of related disability and premature death. The direct medical costs of diabetes may be calculated as both medical expenses attributable to diabetes and total medical expenditures incurred among patients with diabetes. In 1997 in the United States, direct medical expenditures attributable to diabetes totaled \$44.1 billion. This overall amount consisted of \$7.7 billion for diabetes and acute glycemic care, \$11.8 billion due to the excess prevalence of related chronic complications, and \$24.6 billion due to the excess prevalence of general medical complications. Analysis of cost categories showed that 62% of costs were for inpatient care, 25% were for outpatient services, and 13% were for nursing home care. In addition, indirect costs included \$17 billion from premature mortality and \$37.1 billion from disability, a total of \$54.1 billion.

Comparative Medical Expenditures

In 1997, total medical expenditures in the United States for people with diabetes were \$77.7 billion or \$10,071 per capita, in comparison with \$2,669 per capita for those without diabetes. For 1992, one study reported similar figures of \$9,493 and \$2,604, respectively, and noted that 15% of the national healthcare expenditures were spent on treating the 10.3 million people with overt diabetes. It has been estimated that another 5.4 million people have undiagnosed diabetes, a factor that would further increase the estimates of healthcare costs for those with diabetes.

Effectiveness of Intensive Management

Since the publication of the findings of the Diabetes Control and Complications Trial (DCCT) and, more recently, of the UK Prospective Diabetes Study Groups (UKPDS), it has become clear that tighter control of blood glucose in both type 1 and type 2 diabetes can result in significant reduction in the development and progression of microvascular complications of diabetes. Furthermore, the frequency of macrovascular complications is decreased by near-normalization of the blood glucose levels. Multiple contributing causative factors of macrovascular complications, including dyslipidemia and hypertension, make the statistical correlation between blood glucose and macrovascular complications less definite; nonetheless, they are associated variables.

Although the intensive management of diabetes, which is necessary for achievement of tighter blood glucose control, is associated with higher "up-front

costs" of labor, medications, and supplies, this investment has been shown to be effective in reducing morbidity and mortality as well as minimizing later expenditures for the most costly long-term complications. The cost benefit of tight glucose control is most pronounced in young patients who, in general, will have a longer subsequent duration of life during which the complications of diabetes could develop if normoglycemia is not achieved.

The cost of treating diabetes with "intensive" therapy within the DCCT (\$4,014/yr) was 2.4 times that of "conventional therapy" (\$1,666/yr). This cost was in a research setting. Inpatient initiation of treatment during the study accounted for more than 80% of the additional cost. Outside the DCCT study participants, in physician practices, however, intensive therapy was much less expensive—only \$2,337/yr. This difference was primarily due to less frequent and less prolonged use of hospital services and a lower cost for outpatient visits. Dedicated diabetes management teams led by an endocrinologist have been shown to maintain DCCT-level control of diabetes while using fewer inpatient and emergency department resources.

A simulation model of disease progression and costs revealed that intensively treated patients with diabetes live 5.1 years longer than those given conventional therapy, with a lifetime increment in cost of only \$33,746 or \$6,616 per year of additional life. Therefore, the intensive treatment represented an extremely cost-effective investment. In addition, with further consideration of the reduction in complications (blindness, end-stage renal disease, and lower extremity amputation) that decrease the quality of life, the study noted that the incremental cost per "quality-adjusted life year" gained was only about \$20,000 for type 1 diabetes and \$16,000 for type 2 diabetes—relatively inexpensive in relationship to other commonly accepted medical therapies.

Short-term outcome analysis has shown that improved glycemic control in patients with type 2 diabetes is associated with improved quality of life, higher retained employment, greater productive capacity, and less absenteeism. When these factors are considered, the cost of intensive therapy seems offset by even greater economic benefit, not only to the individual patient but to society as a whole.

In the UKPDS, tight control of blood pressure was shown to confer additional preventive benefit. Although this effort increased the average cost of drugs by £ 613 (\$977 US equivalent), a decrease in complications necessitating hospitalization accounted for a reduction of £ 700 (\$1,116 US equivalent). Tight control was estimated to cost less than £3,000 (\$4,784 US equivalent) per year of life gained. Thus, intensive diabetes management makes as much sense economically as it does medically.

Numerous studies have documented the importance of a diabetes management team led by a clinical endocrinologist in achieving the tight blood glucose control necessary to yield the benefits of reduction in human pain and suffering. Such studies have demonstrated the cost efficiency of this approach to diabetes care in reducing the frequency of unnecessary visits to the emergency department and short hospital stays, in decreasing the duration of hospital stay for patients with diabetes, in treating diabetic ketoacidosis more efficiently, and in providing

ongoing care to patients with diabetes that reduced both cardiovascular and renal morbidity and mortality.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Twenty-three physicians are acknowledged as reviewers in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The American Association of Clinical Endocrinologists (AACE) System of Intensive Diabetes Self-Management is divided into three phases. Phase I provides the opportunity for the initial patient assessment. Initial patient education and formulation of a customized therapeutic approach may require several outpatient visits during a period of a few weeks. Phase II, the follow-up phase, provides for interim assessments of the patient's physical condition, reaction to intensive therapy, and understanding of the tools for diabetes self-management. Phase III consists of the ongoing assessment of the complications of diabetes mellitus as well as reeducation of the patient and encouragement to maintain enthusiasm for the very difficult task of intensively managing blood glucose levels.

Phase I: Initial Assessment		Schedule: Multiple visits over 3 to 4 weeks
Goals	Diagnostic Tools	Action Steps
Assess patient's disease status and risk factors	<p>Complex history</p> <ul style="list-style-type: none">• Medical (including chief complaint, duration of known disease)• Family, personal• Gestational• Weight/nutrition• Exercise• Treatment• Symptoms of complications• Risk factors <p>Complex physical</p>	<p>Develop recommendations for</p> <ul style="list-style-type: none">• Nutrition• Exercise• Medication• Blood glucose self-monitoring• Record keeping <p>Schedule appropriate modular evaluation and/or referrals for complications and/or risk factor modification</p>

Phase I: Initial Assessment		Schedule: Multiple visits over 3 to 4 weeks
Goals	Diagnostic Tools	Action Steps
	<p>examination to be done by clinical endocrinologist or other physician</p> <ul style="list-style-type: none"> • Height/weight • Blood pressure (including orthostatic) • Ophthalmoscopy • Thyroid palpation • Cardiac assessment • Pulses • Feet • Skin • Neurologic system <p>Complex laboratory tests to be done and evaluated by clinical endocrinologist or other physician</p> <ul style="list-style-type: none"> • Fasting or random plasma glucose • Glycosylated hemoglobin • Fasting lipid profile • Serum electrolytes • Serum creatinine • Urinalysis • Thyrotropin • Microalbuminuria • Creatinine clearance • Electrocardiography, stress test 	
<p>Assess patient's knowledge base and motivation to learn</p> <p>Initiate appropriate level of diabetes education</p>	<p>Objective tests</p> <ul style="list-style-type: none"> • Diabetes Assessment and Teaching Record* • American Association of Clinical 	<p>Initiate discussion of diabetes self-management topics</p> <p>Refer to</p> <ul style="list-style-type: none"> • Diabetes educator (1 to 2 hours as

Phase I: Initial Assessment		Schedule: Multiple visits over 3 to 4 weeks
Goals	Diagnostic Tools	Action Steps
	<p>Endocrinologists (AACE) Knowledge Evaluation Forms*</p> <p>Psychologic tests</p> <ul style="list-style-type: none"> Michigan Diabetes Research and Training Center Diabetes Care Profile Millon Behavioral Health Inventory <p>Support systems evaluation</p> <ul style="list-style-type: none"> Family Financial Employment <p>*Available in the appendix of the original guideline document (See "Companion Documents" field)</p>	<p>soon as possible)</p> <ul style="list-style-type: none"> Dietitian (1 to 2 hours as soon as possible) Exercise physiologist, if necessary Psychologist, if necessary
Obtain patient agreement to intensive diabetes treatment and initiate diabetes self-management	Patient-physician contract	<p>Explain</p> <ul style="list-style-type: none"> Pathophysiologic features of diabetes Rationale for intensive treatment Patient role in diabetes self-management <p>Provide instructions regarding</p>

Phase I: Initial Assessment		Schedule: Multiple visits over 3 to 4 weeks
Goals	Diagnostic Tools	Action Steps
		<ul style="list-style-type: none"> • Blood glucose self-monitoring • Medication (including dosage-adjustment algorithms) • Nutrition • Exercise • Complications • Special situations • Preventive care • Psychologic aspects <p>Review schedule of follow-up communications (telephone, office visits) among patient, clinical endocrinologist, and health-care team</p>

Phase II: Follow-Up Assessments		Schedule: 3-month intervals (in combination with complications modules)
Goals	Diagnostic Tools	Action Steps
Evaluate blood glucose control and disease complications	<p>Interim history</p> <ul style="list-style-type: none"> • Acute problems • Chronic problems • Hypoglycemia • New symptoms suggestive of complications • Change in risk factors <p>Laboratory tests</p>	<p>Revise recommendations for</p> <ul style="list-style-type: none"> • Nutrition • Exercise • Medications (including dosage-adjustment algorithms) • Blood glucose self-monitoring • Follow-up communications

Phase II: Follow-Up Assessments		Schedule: 3-month intervals (in combination with complications modules)
Goals	Diagnostic Tools	Action Steps
	<ul style="list-style-type: none"> • Random plasma-glucose • Glycosylated hemoglobin • Lipids, if necessary <p>Results of blood glucose self-monitoring</p> <p>Physical examination</p> <ul style="list-style-type: none"> • Height/weight • Blood pressure (including orthostatic) • Ophthalmoscopy • Thyroid palpation • Cardiac assessment • Pulses • Feet • Skin • Neurologic system 	<p>between patient and health care team</p> <p>Make any necessary adjustments to scheduling of complications modules (see Phase III)</p>
6-Month Visit		
<p>Evaluate patient's understanding of diabetes mellitus and rationale for self-management</p> <p>Assess patient's self-management skills</p>	<p>Objective tests</p> <p>Psychologic tests</p> <p>Support systems reevaluation</p>	<p>Initiate intensive education in areas of deficiency, if necessary.</p> <p>Refer (as needed) to</p> <ul style="list-style-type: none"> • Diabetes educator • Dietitian • Exercise physiologist • Psychologist

Phase III : Assessment of Complications		Schedule: Each module to be performed annually Initiate at 9-month visit
Goals	Diagnostic Tools	Action Steps
Retinal Module	<p>Module-specific follow-up assessment including ophthalmoscopy</p> <p>Test of visual acuity (Snellen chart)</p> <p>Funduscopy examination and photographs (if indicated)</p> <p>Intraocular pressure test</p>	<p>Educate patients about retinal complications</p> <p>Determine frequency of follow-up, on the basis of presence or absence of complications</p> <p>Refer to ophthalmologist, on the basis of age and duration of disease and findings on current examination</p>
Cardiac-Cerebrovascular-Peripheral Vascular Module	<p>Module-specific follow-up assessment, including pulses, orthostatic hypotension and cardiac risk factors</p> <p>Electrocardiography and rhythm strip (R-R variation), on the basis of age and symptoms</p> <p>Lipid profile (cholesterol, triglycerides, high-density and low-density lipoproteins)</p>	<p>Educate patient about vascular complications</p> <p>Determine frequency of follow-up, on the basis of presence or absence of complications and cardiac risk factors</p> <p>Consider more intensive cardiac testing (such as stress test) or referral to cardiologist, on the basis of findings on current examination</p>
Renal Module	<p>Module-specific follow-up assessment</p> <p>Laboratory tests</p> <ul style="list-style-type: none"> • 24-hour microalbuminuria • Creatinine clearance • Serum chemistry analysis 	<p>Educate patient about renal complications</p> <p>Determine frequency of follow-up, on the basis of presence or absence of complications</p> <p>Refer to dietitian for instructions on modifications of protein intake, if needed</p>
Neuropathy Module	Module-specific follow-up	Educate patient about

Phase III : Assessment of Complications		Schedule: Each module to be performed annually Initiate at 9-month visit
Goals	Diagnostic Tools	Action Steps
	<p>assessment, including thorough foot examination</p> <p>Review of symptoms relevant to peripheral nerve and autonomic dysfunction</p> <p>Module-specific testing</p> <ul style="list-style-type: none"> • Vibratory sensation • Soft-touch • Pinprick 	<p>neuropathologic complications</p> <p>Determine frequency of follow-up, on the basis of presence or absence of complications</p> <p>Refer to neurologist, if needed</p>

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A key component of the American Association of Clinical Endocrinologists (AACE) System of Intensive Diabetes Self-management is a patient-physician contract. A thriving patient-physician relationship and a partnership effort among the patient, the physician, and the diabetes management team remain critical to the success of intensive diabetes self-management. These coordinated efforts should result in normalization or near normalization of the patient's glycosylated hemoglobin value and blood glucose level. The outcome will be an enhancement in the patient's quality of life, a decrease in morbidity, and a reduction in mortality.

Subgroups Most Likely to Benefit:

Although the benefit of a more comprehensive and intensive approach for diabetes care is evident at any point in the course of patient care, it is particularly important early during the course of the disease. The greatest benefits have been noted in patients with less advanced disease.

POTENTIAL HARMS

- Hypoglycemia is a threat during treatment, although it appears to be less serious with type II diabetes than with type I diabetes mellitus.
- The original guideline document lists other potential adverse reactions occurring with common types of oral drug therapy for type 2 diabetes mellitus.

CONTRAINDICATIONS

CONTRAINDICATIONS

The original guideline document lists contraindications to common types of oral drug therapy used in type II diabetes mellitus.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The primary requirements for the successful implementation of the American Association of Clinical Endocrinology (AACE) System of Intensive Diabetes Self-Management are active patient participation, a committed health-care team, and adherence to the schedule of recommended interactions between the patient and the health-care team.

The health-care team should be managed by a clinical endocrinologist; ideally, the team should include a diabetes-trained nurse, a dietitian skilled in diabetes education, and, as needed, a pharmacist, psychologist, and exercise physiologist. The team should be led by a clinical endocrinologist or other physician who has expertise and experience in overseeing and directing this integrated system of care. Of course, notable improvement in patient care will be achieved when physicians of all specialties are more aware of the relationship between blood glucose control and diabetes-associated complications and are familiar with the steps for implementing a program of intensive diabetes treatment.

A key component of the system of care is a patient-physician contract (sample included in the appendix to the original guideline document), which maintains the preeminence of the patient-physician relationship and the importance of the patient's participation in personal care.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82. [96 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jan (revised 2002 Jan)

GUIDELINE DEVELOPER(S)

American Association of Clinical Endocrinologists - Medical Specialty Society
American College of Endocrinology - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Diabetes Medical Guidelines Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Stanley Feld, MD, MACE, Chairman; Richard Hellman, MD, FACE; Richard A. Dickey, MD, FACP, FACE; Paul S. Jellinger, MD, FACE; John J. Janick, MD, FACE; Helena W. Rodbard, MD, FACE; Rhoda H. Cobin, MD, FACE; David S. H. Bell, MB, FACE; Om Ganda, MD, FACE; Eugene T. Davidson, MD, MACE; John A. Seibel, MD, FACE

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It is an update of the previous version: The AACE medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management. 2000 update. Endocr Pract 2000 Jan-Feb; 6(1): 42-84.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American Association of Clinical Endocrinologists \(AACE\) Web site](#).

Print copies: Available from American Association of Clinical Endocrinologists, 1000 Riverside Ave, Suite 205, Jacksonville, FL 32204.

AVAILABILITY OF COMPANION DOCUMENTS

The following are included in the Appendix to the guideline:

- Diabetes assessment and teaching record. In: The American Association of Clinical Endocrinologists medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Appendix. Endocr Pract 2002 Jan-Feb; 8(1): 66-70.
- AACE knowledge evaluation form. In: The American Association of Clinical Endocrinologists medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Appendix. Endocr Pract 2002 Jan-Feb; 8(1): 71-7.
- Sample patient-physician contract. In: The American Association of Clinical Endocrinologists medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Appendix. Endocr Pract 2002 Jan-Feb; 8(1): 78.

Electronic copies: Available in Portable Document Format (PDF) from the [American Association of Clinical Endocrinologists \(AACE\) Web site](#).

Print copies: Available from AACE, 1000 Riverside Ave, Suite 205, Jacksonville, FL 32204.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 1, 2000. The summary was verified by the guideline developer as of March 8, 2000. This summary was

updated on April 16, 2002. The information was verified by the guideline developer on November 11, 2002.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

All rights reserved. No part of these materials may be reproduced or retransmitted in any manner without the prior written permission of American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE).

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004

The logo for FIRSTGOV, with "FIRST" in blue and "GOV" in red, and a small red star above the "I".

